DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 1-20 in the reply filed on 06/30/2009 is acknowledged.

Claim Objections

2. Claims 8 and 9 are objected because appear to have been amended but fail to include the appropriate status identifiers and markings required by 37 C.F.R. 1.121(c).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 8 recites the limitation "the holding device ". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> ((e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hsu et al. (US 6,468,285).

Regarding claim 15, Hsu et al. discloses a device capable of elongating muscle for treatment of a dilated heart valve, comprising: at least one connecting rod (12); a first clamping device (11) fixed to the at least one connecting rod; and a second clamping device (21) slidably disposed along the connecting rod (Fig. 1; col. 4, ln. 29 - col. 5, ln. 26), wherein the first clamping device and the second clamping device have a first diameter (jaws in the open position) in a delivery configuration and a second diameter (jaws in the closed position) in a clamping configuration, the second diameter less than the first diameter.

Regarding claim 16, Hsu et al. disclose at least one stop disposed on the at least one connecting rod (col. 4, ln. 48 - col. 5, ln. 26).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-4, 9, 10, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherts (US 5,792,149) in view of Hsu et al. (US 6,468,285).

Regarding claims 1, 2 , and 15, Sherts et al. disclose a system capable of treating a dilated heart valve comprising: a delivery device comprising a delivery catheter (110) and a holding catheter (114); a clamping device (118) coupled to the holding catheter adjacent to the distal end of the holding catheter and received in the delivery catheter (Fig. 7, 8), wherein when the system is delivered to a muscle region, the muscle elongation device is released from the delivery catheter and the at least one clamping device wraps around the muscle region (180;

Fig. 19 and 22), and wherein the clamping device has a first diameter in a delivery conformation (Fig. 19) and a second diameter in a clamping configuration (Fig. 22), the second diameter less than the first. Sherts et al. fail to disclose the at least one clamping device slidably disposed on an at least one connecting rod. Hsu et al. disclose a pair of bulldog clamps (11, 21) joined by a connecting rod (12), wherein one clamping device is fixedly attached to the connecting rod and the other is slidably disposed on the connecting rod (col. 4, ln. 48-51). Hsu et al. discloses that paired vascular clamps greatly simplify laparoscopic reconstructive surgery by providing an instrument for adjusting the distance between the tissues in a controlled fashion. Hsu et al. further disclose that the clamps can be assembled before insertion into the body or intracorporeally, either before or after attachment to the tissue (col. 1, ln. 41-57). It would have been obvious to one of ordinary skill in the art to modify the clamp of Sherts et al. to provide paired clamps connected by a connection rod wherein one clamp is fixed and the other is slidably disposed on the connecting rod to achieve the advantage of controlled adjustment of the distance between tissues as suggested by Hsu et al.

Regarding claims 3 and 4, Sherts et al. in view of Hsu et al. disclose the delivery catheter (110) further comprises a side delivery port located adjacent the distal end of the delivery catheter, the side delivery port comprising two restraining members (Fig. 8).

Regarding claims 9, 10, 17, and 18, Sherts et al. disclose the clamping devices comprise an elastic shape-memory material (col. 6, ln. 19-25).

Regarding claims 13 and 16, Sherts et al. in view of Hsu et al. disclose the connecting rod comprises at least one stop disposed at a proximal end of the connecting rod (col. 4, ln. 48 - col. 5, ln. 26).

Regarding claim 14, Sherts et al. in view of Hsu et al. disclose the connecting rod comprises a second stop at a distal end of the connecting rod in that the first clamp (11) is fixedly attached to the connecting rod (col. 4, ln. 29-47).

10. Claims 1, 2, and 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US 7,338,503) in view of Hsu et al. (US 6,468,285).

Regarding claims 1, 2 , and 15, Rosenberg et al. disclose a system capable of treating a dilated heart valve comprising: a delivery device comprising a delivery catheter (52) and a holding catheter (60); a clamping device (10, 100, 200, 300, 400, 500, 600, 800) coupled to the holding catheter adjacent to the distal end of the holding catheter and received in the delivery catheter (Fig. 5-8), wherein when the system is delivered to a muscle region, the muscle elongation device is released from the delivery catheter and the at least one clamping device wraps around the muscle region (Fig. 8), and wherein the clamping device has a first diameter in a delivery conformation (Fig. 6) and a second diameter in a clamping configuration (Fig. 8), the second diameter less than the first. Rosenberg et al. fail to disclose the at least one clamping device slidably disposed on an at least one connecting rod. Hsu et al. disclose a pair of bulldog clamps (11, 21) joined by a connecting rod (12), wherein one clamping device is fixedly attached to the connecting rod and the other is slidably disposed on the connecting rod (col. 4, ln. 48-51). Hsu et al. discloses that paired vascular clamps greatly simplify laparoscopic reconstructive surgery by providing an instrument for adjusting the distance between the tissues in a controlled fashion. Hsu et al. further disclose that the clamps can be assembled before insertion into the body or intracorporeally, either before or after attachment to the tissue (col. 1, ln. 41-57). It would have been obvious to one of ordinary skill in the art to modify the clamp of Rosenberg et al. to provide paired clamps connected by a connection rod wherein one clamp is

fixed and the other is slidably disposed on the connecting rod to achieve the advantage of controlled adjustment of the distance between tissues as suggested by Hsu et al.

Regarding claim 8, Rosenberg et al. disclose the holding device comprises biopsy forceps (62).

Regarding claims 9, 12, 17, and 20, Rosenberg et al. disclose the clamping devices comprise a shape-memory material chosen from a group consisting of stainless steel, nitinol, tantalum, cobalt nickel alloy, platinum, titanium, a thermoplastic or thermoset polymer, or a combination thereof (col. 8, ln.27-65). (col. 8, ln.27-65).

Regarding claims 10 and 18, Rosenberg et al. disclose the shape-memory material is an elastic shape-memory material (col. 8, ln. 27-65).

Regarding claims 11 and 19, Rosenberg et al. disclose the shape-memory material is a thermal shape-memory material (col. 8, ln. 32-33).

Regarding claims 13 and 16, Rosenberg et al. disclose in view of Hsu et al. disclose the connecting rod comprises at least one stop disposed at a proximal end of the connecting rod (col. 4, ln. 48 - col. 5, ln. 26).

Regarding claim 14, Rosenberg et al. disclose n view of Hsu et al. disclose the connecting rod comprises a second stop at a distal end of the connecting rod in that the first clamp (11) is fixedly attached to the connecting rod (col. 4, ln. 29-47).

11. Claims 1, 2, 5, 7, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapacki et al. (US 5,569,274) in view of Hsu et al. (US 6,468,285).

Regarding claims 1, 2 , and 15, Rapacki et al. disclose a system capable of treating a dilated heart valve comprising: a delivery device comprising a delivery catheter (3) and a holding catheter (21); a clamping device (2) coupled to the holding catheter adjacent to the distal end of the holding catheter and received in the delivery catheter (Fig. 4A-B), wherein

when the system is delivered to a muscle region, the muscle elongation device is released from the delivery catheter and the at least one clamping device wraps around the muscle region (Fig. 9), and wherein the clamping device has a first diameter in a delivery conformation (Fig. 8) and a second diameter in a clamping configuration (Fig. 9), the second diameter less than the first. Rapacki et al. fail to disclose the at least one clamping device slidably disposed on an at least one connecting rod. Hsu et al. disclose a pair of bulldog clamps (11, 21) joined by a connecting rod (12), wherein one clamping device is fixedly attached to the connecting rod and the other is slidably disposed on the connecting rod (col. 4, ln. 48-51). Hsu et al. discloses that paired vascular clamps greatly simplify laparoscopic reconstructive surgery by providing an instrument for adjusting the distance between the tissues in a controlled fashion. Hsu et al. further disclose that the clamps can be assembled before insertion into the body or intracorporeally, either before or after attachment to the tissue (col. 1, ln. 41-57). It would have been obvious to one of ordinary skill in the art to modify the clamp of Rapacki et al. to provide paired clamps connected by a connection rod wherein one clamp is fixed and the other clamp is slidably disposed on the connecting rod to achieve the advantage of controlled adjustment of the distance between tissues as suggested by Hsu et al.

Regarding claim 5, Rapacki et al. disclose delivering the clip and clip applier through a trocar sleeve (121) or "locating device (Fig. 7 and 8).

Regarding claims 5 and 7, Rapacki et al. as modified by Hsu et al. disclose the system comprising a guide wire (23) locating device (Figure 2A-2C).

Regarding claims 13 and 16, Rapacki et al. in view of Hsu et al. disclose the connecting rod comprises at least one stop disposed at a proximal end of the connecting rod (col. 4, ln. 48 - col. 5, ln. 26).

Regarding claim 14, Rapacki et al. in view of Hsu et al. disclose the connecting rod comprises a second stop at a distal end of the connecting rod in that the first clamp (11) is fixedly attached to the connecting rod (col. 4, ln. 29-47).

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapacki et al. (US 5,569,274) in view of Hsu et al. (US 6,468,285) as applied to claim 5 above, and further in view of Allgood (US 5,122,122).

Regarding claim 6, Rapacki et al. fail to disclose the trocar sleeve or "locating device" comprises a balloon. Allgood discloses a trocar sleeve comprising an inflatable balloon for anchoring the trocar sleeve from moving at the incision site (col. 1, ln. 5-10 and col. 5, ln. 4-9). It would have been obvious to one of ordinary skill in the art to modify the trocar sleeve or "locating device" of Rapacki et al. to include a balloon in order to anchor the trocar sleeve within the incision.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
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